22. An apparatus for determining an intra-procedural blood flow in a vascular corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter;

(c) means for effecting the corrective produce; and

(d) a blood parameter sensor connected to the catheter and spaced from the altering section.

Please add the following new claims:

30. The apparatus of Claim 1, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

31. The apparatus of Claim 1, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

32. The catheter of Claim 9, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

33. The catheter of Claim 9, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

REMARKS

In response to the Office Action mailed October 19, 1999, the present application has been carefully reviewed and amended. Applicant thanks Examiner Szmals for his particular attention to the claims.

The present invention relates to a method and apparatus for the real time determination of flow during procedures to correct a vascular dysfunction. By

determining an intra-procedural flow, the effectiveness of a surgical revision may be promptly assessed and appropriate remedial action taken, without requiring reinsertion of the catheters or guide wires. As a physician can immediately and accurately determine intervention effectiveness, the procedure may be "tuned" to provide optimal flow.

Rejections Under 35 U.S.C. §102

Claims 19, 20 and 22-24 stand rejection under 35 U.S.C. § 102(b) as being anticipated by Williams, et al. ("Williams") Examiner Szmal states "Williams et al. discloses a device for thermal dilution by heat exchange through a catheter wherein Claims 19, 20 and 22-24 discussed in Column 4 and seen in Figure 1 the collation for blood flow as described in Column 7, Lines 21-4." [Paper 3, Page 2]

Claim 19

As amended, independent Claim 19 recites in part, "inserting a catheter into a vessel" and "employing the catheter to perform a vascular correction in the vessel."

Applicant has reviewed Williams and is unable to identify any structure or disclosure in Williams of performing a vascular corrective procedure, much less determining a blood flow during such procedure.

The structure set forth in Col. 2, lies 64-66 of Williams is a balloon which can be inflated to just stop the flow of blood and match the corresponding periphery of the vessel. (Col. 3, lines 38-54)

In fact, Examiner Szmal states on page 3 of Paper 3, "Williams et al. however, does not disclose a method of locating a blood parameter altering section in the vessel, *performing a stenosis reduction procedure*, and a stenosis reduction procedures includes angioplasty." [Emphasis added]

Thus, as Claim 19 clearly recites the performance of a vascular correction and Williams does not disclose and cannot perform such step, Applicant respectfully submits Claim 19 cannot be anticipated by Williams.

Claim 20

Independent Claim 20 recites, in part, "a catheter having means for increasing the effect of size of a portion of the vascular passage."

Williams does not disclose a means for increasing the effective portion of the vascular passage. The structure relied upon by Examiner Szmal is a balloon having a thickness of "one-twentieth to one-tenth millimeter and is preferable for high flexibility and rapid heat transfer. It is also preferable because it only negligibly adds to the outer diameter of the catheter in the balloon region." (Column 7, Lines 43-47)

Williams continues "the balloon need not be inflated so fully that it becomes a rigid cylinder, but rather it may be inflated only partially...An underinflated balloon will conform better to the shape of the blood vessels in cardiac chamber in which the balloon passes and which it eventually is located for measurement. This conformance may be an advantage for maintaining blood flow and reducing the likelihood of trauma to the blood vessel." (Column 7, Lines 49-60)

That is, the Williams balloon does not vary the size of a portion of the vascular passage. In fact, Williams expressly seeks to "conform" to the vascular passage, as it may "be an advantage for maintaining blood flow and reducing the likelihood of trauma to the blood vessel." (Col. 7, lines 55-60)

As Williams does not disclose each recited limitation, Applicant respectfully submits a rejection of 35 U.S.C. § 102(b) cannot be sustained.

Claim 22

Independent Claim 22 recites in part "means for perfecting the corrective procedure."

Again, as the Williams patent does not disclose or suggest a device for effecting a corrective procedure on a vascular flow nor such means in connection with a blood parameter altering section on the catheter, Applicant respectfully submits Claim 22 cannot be a rejection on 35 U.S.C. §102(b).

Further, Examiner Szmal states "Williams does not disclose performing a stenosis reduction procedure and the stenosis reduction procedure including angioplasty." [Paper 3, page 3] Therefore, Applicant respectfully submits Claim 22 is in condition for allowance.

As Claims 23 and 24 depend from Claim 22 and include all limitations thereof, Applicant respectfully submits these claims are also a condition for allowance.

Rejections Under 35 U.S.C. §103

Claims 25, 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Williams in view Salo et al. ("Salo") Examiner Szmal relies upon Salo to disclose a dimension sensitive angioplasty catheter method wherein a blood parameter altering section is located; performing a stenosis reduction in a procedure; and the stenosis reduction procedure includes angioplasty. [Paper 3, Page 3]

Claim 25

Independent Claim 25 recites, in part, "locating a blood parameter altering section in the vessel; locating a blood parameter sensor downstream of the altering section; performing the stenosis reducing procedure; and

determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor."

In contrast, Salo is specifically directed to a dimension sensitive angioplasty catheter. That is, Salo provides a plurality of electrodes and a signal generators for determining a cross-sectional size of a blood vessel to provide an indication of the relative size of a lumen of the blood vessel. There is no disclosure or suggestion in Salo to employ the alteration of a blood parameter. In fact, Salo is specifically directed to measuring "the cross-sectional size of the blood vessel being traversed by the catheter." (Column 2, Lines 41-45)

While the Examiner asserts it would have been obvious to one of ordinary skill in the art to modify the invention of Williams to include the locating of blood parameter altering sections in performing angioplasty stenosis reducing procedure, Applicant respectfully submits that such proposed modification is contrary to both references and the only suggestion for the modification is Applicant's disclosure.

Williams does not disclose or suggest vascular correction, stenosis reduction or angioplasty. Williams is specifically directed to the determination of a flow rate by thermal dilution heat exchange wherein a cold liquid in a sealed balloon or sheath along the catheter is disposed in the blood stream. Specifically, as Williams sets forth a definition of a process of the invention in the broadest and most general form (Col. 3, Lines 7-8)

> The process includes the step of removing heat from the blood flowing through the body by heat exchange at the position along the

flow path, without liquid injection into the blood. (Col. 2, Line 67-68 and Col. 3, Lines 1 and 2)

With respect to Salo., Salo states that "by suitable selection of the driving frequency, the characteristics of the lesion can be determined." ([Col. 1, Lines 29-32) Salo does not alter or change a blood parameter. That is, electrical sensors of Salo may make impedance measurements which impedance measurements are proportional to the cross-sectional area of the portion of the vessel disposed between two impedance electrodes. That is, a blood parameter is not altered but rather the electrical impedance of a given cross-section of the vessel is measured and converted to a cross-sectional area. Therefore, Applicant respectfully submits the primary justification for a combining these references in Applicant's disclosure is hindsight in view of Applicant's disclosure.

As the primary reference does not disclose or suggest the use of a stenosis reducing procedure and the secondary reference does not alter a blood parameter, Applicant respectfully submits Claim 25 as it complies with 35 U.S.C. §103.

As Claim 26-29 depend from Claim 25 and include all limitations thereof, Applicant respectfully submits these claims are also in condition for allowance.

Claims 1-7 and 9-15

Claims 1-7 and 9-15 stand rejected under 35 U.S.C. §103 as being unpatentable over Bryant in view of Tanabe et al. ("Tanabe")

Examiner Szmal asserts that "Bryant discloses a blood flow measuring method wherein the apparatus includes an elongated catheter having an angioplasty balloon (See Column 2, Line 64-66)" [Paper 3, Page 4].

Applicant respectfully submits Bryant does not disclose an angioplasty balloon. Bryant specifically states:

> An inflatable balloon 23 is secured to the outer surface of the catheter shank 24 in a fluid-type manner in order to establish a selectively inflatable chamber 25 in the torus that is formed between the inner surface of the balloon and the outer surface of the shank. [Col. 2, lines 64-66]

Bryant continues:

> In operation, the catheter 10 is inserted through an incision (not shown), into the blood vessel 11 and is lodged in a desired, predetermined location by observing, for example, graduations on the catheter that measure the length the catheter has travelled through the blood vessel. When in place, the pump 35 is activated *to inflate the balloon 23 to a degree that just completely obstructs the flow of the blood 12 through the vessel 11*. Complete obstruction of the blood vessel 11 is registered by noting the downstream blood pressure registered on the gage 31. When the blood pressure gage 31 indicates zero blood pressure downstream from the balloon 23, it can be assumed that the flow of blood past the balloon 23 has stopped and that *the maximum circumference of the balloon matches the corresponding circumference of the adjacent part of the blood vessel 11.* [Col. 3, lines 38-54, Emphasis added]

That is, Bryant does not have "a stenosis reducing portion." In contrast, Bryant merely inflates to "just completely obstruct the flow of blood." Therefore, if the vessel were healthy or subject to stenosis, Bryant would not alter the vessel. To do so would be contrary to the express purpose of Bryant.

Claim 1 further recites "a blood property change port." As stated by Examiner Szmal, Bryant does not disclose the use of a blood property change port and a down stream sensor.

Not only does Bryant not disclose a blood property change port, but a blood property change port would be directly contrary to Bryant. Specifically, Bryant states "This invention is a significant improvement over the prior art. *Foreign matter, e.g., saline solution, is* ***not*** *added* to the blood stream, thereby reducing the degree of risk to the patient." [Emphasis added; Column 2, Lines 16-19]

Tanabe does not cure the deficiencies of Bryant. Tanabe does not disclose a stenosis reducing portion or even an angioplasty balloon. The balloon 17 of Tanabe is a "latex rubber, polyurethane elastomer, synthetic rubber or silicone rubber" member which is "inflated to block the pulmonary artery so that the pulmonary arterial wedge pressure can be determined." (Col. 38-69 and Col. 7, line 1)

Applicant respectfully submits the balloon of Tanabe cannot be construed as a stenosis reducing portion of a catheter.

Therefore, Applicant respectfully submits and that Claim 1 is in condition for allowance. As Claims 2-7 depend from Claim 1 include all limitations thereof, Applicant respectfully submits these claims are also in condition for allowance.

Claim 9

With respect to Claim 9, neither Bryant nor Tanabe disclose a stenosis reducing member selectively actuable to reduce a stenosis in a vessel. Therefore, Applicant respectfully submits Claim 9 is also in condition for allowance. As Claims 10-15 depend from Claim 9 and include all limitations thereof, these claims are also in condition for allowance.

Claims 16-18

Claims 16-18 stand rejected under 35 U.S.C. §103 as being unpatentable over Bryant in view of Tanabe in further view of Williams.

Again, Examiner Szmal asserts "Bryant discloses a blood flow measuring catheter wherein there is an expanding angioplasty balloon (See Fig 1)." [Paper 3, Page 6]

Applicant respectfully submits Bryant does not disclose an angioplasty balloon. Specifically, the Bryant balloon is inflated until flow of the blood through the vessel stops. In fact, the Bryant balloon does not distort the vessel as "the maximum circumference of the balloon matches the corresponding circumference of the adjacent portion of the blood vessel 11." (Column 3, Lines 50-54)

These references fail to disclose or suggest the steps of Claim 16, including:

1. introducing a first change in a blood property upstream of the blood property sensor;

2. detecting passage of the first change in the blood property at the blood property sensor;

3. reducing the stenosis of in the vessel;

4. introducing a second change in the blood property upstream of the sensor;

5. detecting passage of the second change in the blood property at the blood property sensor; and

6. determining a change in blood flow corresponding to the detected passage of the first change in the blood property and the second change in the blood property.

That is, there is no disclosure or suggestion in the references to determining a change in blood flow corresponding to changes in a blood property before and after reducing the stenosis of the vessel.

Applicant respectfully submits Claim 16 is in condition for allowance. As Claims 17 and 18 depend from Claim 16 include all limitations thereof, Applicant respectfully submits these claims are also in condition for allowance.

Claim 8

Claim 8 stands rejected under 35 U.S.C. §103 as being unpatentable for Bryant and Tanabe as applied to Claims 1-7 and in further review of Williams.

Applicant respectfully submits the deficiencies of the combination of Bryant and Tanabe are not remedied by reliance upon Williams.

In fact, none of the references disclose or suggest an elongated catheter having a stenosis reducing member. Further, none of the references disclose or suggest the formula of Claim 8. Therefore, Claim 8 is in condition for allowance.

Newly added Claims 30-33

Claims 30-33 depend from Claim 9 and include all the limitations thereof. As these claims more particularly point out and claim the present invention, these claims are also in condition for allowance.

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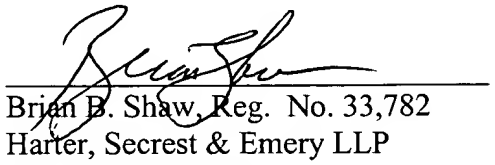
Applicant respectfully submits all the pending claims, Claims 1-33, are in condition for allowance. If Examiner Szmal feels that any issues remain he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,



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